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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 02N-0209, Request for Comment on First Amendment Issues

FDA's regulations implementing the Nutrition Labeling and Education Act (NLEA) have raised first amendment issues with respect to health claims. The Council for Responsible Nutrition (CRN) believes there is an alternative way of implementing the health claims provisions of NLEA that will be compatible with first amendment concerns while still permitting the agency to exercise appropriate oversight and ensure that permitted health claims are truthful and nonmisleading, adequately substantiated by scientific evidence, and supported by significant scientific agreement. CRN is a trade association representing the dietary supplement industry. Members include ingredient suppliers as well as finished product manufacturers.

NLEA Health Claims, including Pearson Qualified Claims

Section 403(r)(1) of NLEA defines a health claim as a statement that "characterizes the relationship of any nutrient....to a disease or a health-related condition...." Section 403(r)(3)(B)(i) provides that such a claim may not be made unless FDA has determined "that there is significant scientific agreement....that the claim is supported by [the totality of publicly available scientific evidence]" and has authorized it by regulation. (Separate provisions applying to FDAMA health claims will not be considered here.)

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02N-0209

Thus, under NLEA a health claim is **a statement about a nutrient/disease relationship** and significant scientific agreement must exist regarding **the claim**. Under the language of NLEA, there is no requirement that the health claim itself must be unqualified, nor any prohibition against a qualified claim. To reiterate, it is the **claim**, not the nutrient/disease relationship itself, which must be the subject of scientific agreement. If FDA adopted this view and permitted health claims accurately describing the balance of the evidence, it could credibly be argued that any claim **not** permitted by such an approach is false and misleading and thus may legally be disallowed under first amendment concepts.

The Pearson decision essentially brings FDA to this position, with regard to health claims for dietary supplements, and logic suggests the position must also encompass health claims for conventional foods. Although dietary supplement health claims were the subject of the Pearson case, the first amendment issue identified by the courts is clearly not limited to any one class of products eligible for NLEA health claims. FDA has determined that the same criteria for health claims apply to dietary supplements that apply to conventional foods, and therefore any first amendment defect also must apply to both categories of food products.

The court found in Pearson that, while FDA may disallow a health claim that it finds to be false or misleading, it may not completely disallow a claim solely because the evidence in support of it fails to reach the standard of significant scientific agreement as FDA currently applies the term. FDA has responded by creating a new class of qualified health claims for dietary supplements, rather than by reconsidering the overall approach to NLEA health claims. CRN believes this is not a sufficient response to satisfy the underlying first amendment concern.

Consider, for example, the case of the omega-3 health claim. It is undeniable that there is scientific evidence in support of the potential benefit of omega-3 fatty acids in reducing the risk of coronary heart disease. There is more positive evidence today than there was when FDA first reviewed the omega-3 health claim, but there was significant evidence even at the time of the initial review. However, FDA declined to approve it and as a consequence essentially banned any revelation in product labeling of the positive balance of the evidence on this subject.

As a result of the Pearson decision and FDA's re-evaluation of the evidence, the agency now says it will tolerate a qualified health claim for omega-3 fatty acids. It is important to note that the claim is not being affirmatively permitted or authorized, but is merely being tolerated (only for dietary supplements) as a matter of enforcement discretion -- an ungainly and reluctant manner of implementing the court's decision. The Pearson claim FDA has agreed to tolerate is: "Consumption of omega-3 fatty acids may reduce the risk of coronary heart disease. FDA evaluated the data and determined that, although there is scientific evidence supporting the claim, the evidence is not conclusive."

CRN suggests that, instead of creating this new category of qualified health claims that are tolerated for a single class of foods as a matter of enforcement discretion, the better approach is to use the court's guidance as the basis of a more cohesive overall regulatory scheme for NLEA health claims. CRN urges FDA to adopt the view that it is possible for a qualified health claim to be supported by significant scientific agreement regarding the positive balance of the evidence and thus be fully acceptable as an NLEA health claim. This reinterpretation of the groundrules should logically apply to all uses of the health claim in question -- for conventional foods as well as for dietary supplements. It would not require or permit health claims that FDA finds to be unsupported by the balance of the evidence. The court in Pearson specifically noted that FDA would be fully justified in denying a claim for which the evidence was more negative than positive, and in fact the agency has denied several qualified claims on these grounds.

Response to FDA's Nine Questions

1. CRN recognizes that drugs are regulated more stringently than foods and dietary supplements, and we do not believe the more reasonable approach we have suggested for NLEA health claims needs to be interpreted in a manner that would undermine or restrict FDA's ability to regulate drug claims appropriately. However, drug regulation is not our expertise, and we leave expansion on this topic to those directly involved.

2. CRN has no position on FDA's policies for regulating the advertising of drugs, biologics, or devices.

3. CRN believes that, in general, there is no basis for distinguishing between claims permitted for conventional foods and those permitted for dietary supplements. In the case of NLEA health claims, the law left the way open for FDA to adopt a different system for dietary supplement health claims, but the agency decided the procedure and standard for health claims should be same for dietary supplements as for conventional foods. Therefore, the treatment should be equal. In the case of DSHEA structure/function claims, the law requires notifications and disclaimers for dietary supplement claims that are not required for structure/function claims appearing on conventional food products. We see no need for conventional food products to be burdened with these requirements. CRN does not know of any basis for believing that consumers approach claims about conventional foods and dietary supplements differently. We do believe qualifications and disclaimers may be necessary in some cases to ensure that a claim is correctly understood by consumers, and we believe such qualifications to be preferable to prohibiting certain statements altogether (and certainly more acceptable in terms of first amendment concerns). All claims and other label information provided to consumers needs to be succinct and understandable. Many of FDA's model health claims suffer from being long and unwieldy. The agency's 1995 proposed modifications are preferable to the original model claims, but have never been finalized. We urge finalization of the streamlined model claims language and adoption of concise language when future model health claims are developed.

4. Whether disclaimers should be in the same type size and of the same prominence as claims will vary on a case by case basis, depending on the importance of the disclaimer and the nature of the claim.

5. Warnings, like claims, should be as succinct as possible while still conveying the necessary information. A standard location and format for warnings, such as that adopted in OTC labeling may be helpful in facilitating consumer use.

6. In the case of conventional foods and dietary supplements, the FD&C Act clearly gives FDA authority to mandate the content of some portions of the label, including the Facts Box, other aspects of the information panel, and some features of the Principle Display Panel. Similar authority does not extend to the layout and content of advertising. The comments submitted to this docket by the Federal Trade Commission (FTC) make it

clear that the standards applied in evaluating product advertising are stringent and yet flexible and may permit some claims that are not allowed in product labeling.

7. CRN has no position on FDA regulation of statements about off-label uses of drug products.

8. CRN does not believe FDA's regulations of health claims and nutrient content claims adequately advance the cause of providing consumers with more information about the nutritional and health-related characteristics of foods and dietary supplements. The alternative CRN has recommended in the main text of these comments would accomplish the objectives of ensuring that NLEA health claims are truthful, nonmisleading, and supported by significant scientific agreement, but would be less restrictive of commercial speech. The current regulations governing nutrient content claims may also be more restrictive than required by NLEA.

9. CRN believes FDA should amend it regulations on NLEA health claims and its guidance on significant scientific agreement in the ways recommended in the text of these comments. The regulations on nutrient content claims may benefit from similar reconsideration.

Respectfully,

for Annette Dickinson

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